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(54) SYSTEMS AND METHODS FOR MANAGING BLOOD DONATIONS

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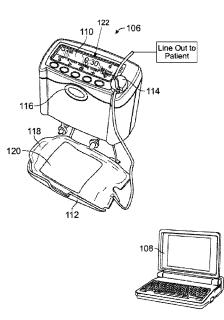
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(57) ABSTRACT

Apparatuses and methods of using them to collect blood, are provided, by first ensuring that the patient's skin is properly cleaned, to prevent contamination of the collected blood. One feature is a blood collection device configured to collect blood from a patient. Another feature is a scrub timer integrated into the device and configured to indicate to a user a scrub time period prior to beginning a blood draw process. The scrub timer can be configured to audibly and/or visually indicate to a user the start and stop times of a scrub cleaning process. In one embodiment, the scrub timer can be restarted, either manually or automatically, if the scrub cleaning process is not followed properly.

27 Claims, 2 Drawing Sheets



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See application file for complete search history.

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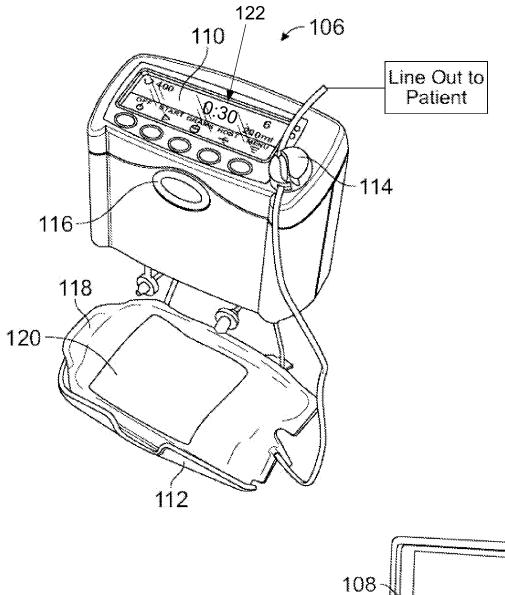
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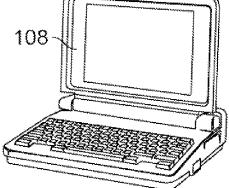
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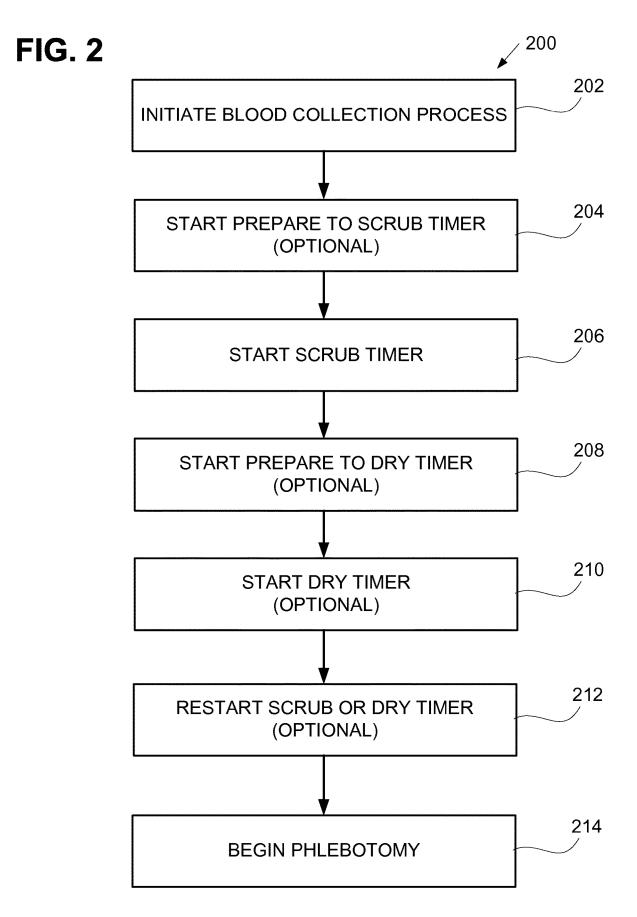
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FIG. 1







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SYSTEMS AND METHODS FOR MANAGING BLOOD DONATIONS

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the benefit under 35 U.S.C. 119 of U.S. Provisional Patent Application No. 62/005,673, filed May 30, 2014, titled "SYSTEMS AND METHODS FOR MANAGING BLOOD DONATIONS". This application is herein incorporated by reference in its entirety.

INCORPORATION BY REFERENCE

All publications, including patents and patent applica-¹⁵ tions, mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.

FIELD

Described herein are devices and methods for use in blood donation and blood management. In particular, described herein are devices and methods for acquiring blood dona- ²⁵ tions.

BACKGROUND

Blood collection from a donor typically requires piercing 30 the subject's skin with a needle, usually after the area of the subject's skin to be pierced is cleaned (e.g., with alcohol, iodine, or the like). Bacteria present on the skin can enter the blood component collecting bag together with the blood. Indeed, it has been found that some kinds of skin-borne 35 bacteria that may enter the blood collecting bag in this manner may multiply even if blood collecting bag is kept cold. When the collected blood is transfused into a patient, the patient may suffer from infectious disease or blood poisoning. 40

Although most phlebotomists are trained in techniques to wash or prepare the skin prior to collecting blood, there is a great deal of variability and simple human error associated with collection of blood. For example, the time required to adequately prepare the skin site for needle penetration, 45 including both washing and drying the skin, is not standardized. Even where standard times are applied for each of these steps (e.g., 30 second scrub time), the phlebotomist is generally expected to time herself or himself. Thus, there is a potential for further error and variability which may result 50 in contamination of the collected blood.

The current technique used by most phlebotomists allows the phlebotomist to use a time piece to time a scrubbing procedure, generally their own watch or a clock on the wall. In many instances, a phlebotomist may use one time piece, 55 such as their watch, to initiate a scrubbing procedure, and may then use another time piece, such as a clock on the wall, to monitor the end of the scrubbing procedure. Non-compliance with standardized scrub times can result when the time is not synchronized between these two time pieces. 60 When non-compliance is observed by the FDA, the blood center can be given a 483 non-compliance write-up and be required to respond with a Corrective and Preventative Action, which costs the blood center both time and money.

In view of this and other problems, there is a need for 65 tools, including blood collection apparatuses that may help address these issues. In particular, described herein are blood

collection devices that are adapted to provide multiple easy-to-use and accurate timers that may guide the phlebotomist in preparing the subject's skin, and can prevent collection from improperly cleaned skin, as well as methods of using such devices.

SUMMARY OF THE DISCLOSURE

In general, described herein are apparatuses and methods 10 of using them to collect blood by first ensuring that the patient's skin is properly cleaned, to prevent contamination of the collected blood. Any of the devices described herein may include an integrated controller with a timer having multiple modes to guide a user (e.g., a phlebotomist) in prepping a subject's skin for a blood draw. The system may include a display (visual) and/or audible output to guide the user, such as a pre-configured countdown for a timer that establishes a predetermined cleaning and drying time (and also potentially additional cleaning/drying cycles). The 20 timer may be hands-free, so that the user only has to trigger the first activation, additional time cycles may be triggered automatically. The system may include a controller that also interfaces with the timer and may record compliance. The system may include a restart function, allowing the user to restart the pre-configured countdown if the cleaning and drying time is missed for any reason. Additionally, the system may include an automated restart function, wherein the pre-configured countdown is restarted if a user reaches the end of the cleaning and drying time without proceeding to the blood collection process for longer than a configured time period.

For example, a blood collection apparatus may include a countdown beep during a preparing to clean (prepare to scrub) period and/or a prepare to dry time period, and/or during a drying period and/or during a cleaning period. In some variations the apparatus or method of operating the apparatus includes a countdown beep only during the preparing time periods (e.g., preparing to clean and preparing to dry time periods). During any of these time periods (first preparing to clean time period, first cleaning time period, second preparing to clean time period, second cleaning time period, preparing to dry time period, drying time periods) a visual countdown may be shown on the display, with or without an audible count down. For example, in some variations a visual countdown may be shown on the display only during the scrub and dry time periods (including displaying without an audible countdown). At the beginning and end of any of these time periods (e.g., the scrub and dry periods), a distinctive audible tone may be made to signal the start or end of that period so the phlebotomist need not be watching the display.

For example, described herein are methods of collecting blood from a patient, the method comprising: initiating, in a blood collection device, a scrub timer having a scrub time period; during the scrub time period, disinfecting tissue of the patient at a needle entry site; and after the scrub time period has elapsed, beginning a blood draw process. The method may include emitting one or more audible beeps from the collection device at the start of the scrub period. The method may include emitting one or more audible beeps from the collection device during the scrub period. The tones emitted may be different. For example, the tones emitted at the start of a preparing to dry period, dry period, preparing to clean period, cleaning period, etc. may be different from each other and from the tones emitted to count down these periods. For example, the tones may be different in frequency, pitch, volume, scale, intensity, etc. Thus, for example, the method may include audibly counting down the scrub time period. For example, the method may include emitting a series of audible beeps counting down the scrub period. In some variations, the method may include: initiating, in the blood collection device immediately after the 5 scrub time period has elapsed, a prepare to dry timer having a prepare to dry time period; and audibly counting down the prepare to dry period. The method may also include initiating, in the blood collection device immediately after the scrub time period has elapsed, a prepare to dry timer having 10 a prepare to dry time period; during the prepare to dry period, performing a secondary wash of the patient at the needle entry site; and audibly counting down the prepare to dry period during the prepare to dry time period. After the disinfecting tissue step, the method (system) may automatically initiate in the blood collection device a dry timer having a dry time period; and drying tissue of the patient at the needle entry site during the dry time period.

For example, described herein are methods of collecting blood from a patient, the method comprising: initiating, in a ²⁰ blood collection device, a scrub timer having a scrub time period; audibly counting down the scrub timer during the scrub time period; automatically initiating, in the blood collection device after the scrub time period has elapsed, a dry timer having a dry time period; audibly counting down ²⁵ the dry timer during the dry time period; and beginning a blood draw process after the dry time period has elapsed. The method may also include initiating, in the blood collection device immediately after the scrub time period has elapsed, a prepare to dry timer having a prepare to dry time ³⁰ period; and audibly counting down the prepare to dry period.

Devices and systems configured to implement these methods are also included. For example, a blood collection device may include: a support configured to hold a blood collection bag; a pinch valve configured to engage a tube ³⁵ leading from the blood collection bag to a patient; a controller configured to control the blood collection device including the pinch valve; and a scrub timer coupled to the controller and configured to indicate to a user a scrub time period prior to beginning a blood draw process. ⁴⁰

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an illustration of a blood collection device and a control system.

FIG. **2** is a flowchart describing an integrated scrub timer in a blood collection device.

DETAILED DESCRIPTION OF THE DISCLOSURE

FIG. 1 is a diagram showing a blood collection device 106 and optional control system 108. In some embodiments, the blood collection device 106 is a standalone device and does not use or interact with a control system 108. In other 55 embodiments, more than one blood collection device 106 can be networked with and bi-directionally communicate with the control system 108. Blood collection device 106 can provide blood banks and other blood collection centers with an inexpensive yet accurate device for managing and 60 monitoring the collection of blood donations from blood donors. The device is configured to accurately weigh blood donations during the collection process, and to provide blood bag mixing to insure correct disbursement of anticoagulant and alleviate the need for manual mixing by a 65 phlebotomist. Referring to FIG. 1, blood collection device 106 can include a graphical user interface (GUI) 110, a scale

or bag tray 112, a pinch valve 114, and a barcode scanner 116. The device can be configured to receive a blood donation bag 118 on the scale and in the pinch valve, as shown. In some embodiments, the blood donation bag comprises a barcode 120 readable via the barcode scanner of the blood collection device.

The GUI **110** allows a user (e.g., a phlebotomist) to configure, calibrate, and setup the blood collection device for use. GUI **110** may display information to the user such as calibration status of the blood collection device **106**. In some embodiments, the GUI **110** displays information to the user such as calibration status of the device bag tray **112**, weight of the blood donation bag **118**, and operation status of the device (e.g., calibration, blood collection underway, blood collection complete, errors during collection, etc.). During initial setup of the device, a user may be asked to zero or calibrate the device, with no weight on the bag tray **112** to ensure accurate measurement of collected blood.

In some embodiments, the device comprises an agitation system suspended on the internal load cell. The agitation system can comprise a motor-driven crank configured to agitate/shake the bag tray **112** and the blood donation bag **118** during blood collection. The agitation system can be designed for minimal weight and optimized for the power required to agitate/shake the bag tray **112** and thus, the blood bag.

When a blood collection bag is placed on the bag tray **112**, vertical oscillations of the agitation system can cause blood collected from a donor to flow from one end of the bag to the other, resulting in gentle mixing of the blood and the contained anticoagulant and/or additives. Since the agitation system is mounted on the internal load cell, the load cell can then sense the weight of the bag tray **112**, the agitation system, the blood bag, and the accumulated blood.

The blood collection device can further include a pinch valve **114** configured to open and close the blood bag line leading from the patient to the blood donation bag **118**. Thus, the blood collection device can be configured to open the pinch valve **114** when the blood collection process begins and close the pinch valve when the blood collection is complete, e.g., when the load cell indicates that the blood donation bag is full.

The blood collection device is configured to automatically 45 measure the weight of accumulated blood during the blood collection process. In some embodiments, the weight of the accumulated blood is measured every time the blood bag and bag tray **112** are in a relatively stable position. In other embodiments, the accumulated blood is measured continu-50 ously. By regularly monitoring the weight of collected blood, the blood collection device can calculate blood flow rates from the patient to the blood collection bag. The weight measurements and or flow rates can be used to determine when the blood collection process is complete.

When a blood collection is started, the blood collection device can first implement a series of weight readings of the empty blood bag, the agitation system, and the bag tray assembly. This can be recorded in the device's memory as the tare weight. The desired collection volume can be converted mathematically from weight to volume by using the specific gravity of blood, e.g., of 1.058. (1.00 ml of blood weighs 1.058 grams); this may be configurable on the device between 1.050 to 1.060. This converted weight value plus the tare weight results in the target weight and is compared against on-going weight readings as the collection proceeds. The blood collection device can then open the pinch valve to begin the blood collection process.

The agitation system can be left off until a small increase in weight is seen over the tare weight. As soon as the weight increase is seen by the blood collection device, the agitation system can initiate the shacking/rocking, and various other timing and flow functions can be activated. The blood 5 collection device can continue to read the weight of the blood collection bag. Although these readings are relatively accurate, in some embodiments for greater accuracy, the blood collection system can stop the agitation process when the total weight is slightly less than the target weight. The 10 final readings of collected blood can then be taken with the bag and bag tray in a horizontal position. At this point, it is unnecessary to continue agitating the bag since the anticoagulant is already fully mixed with the blood in the bag. Alternatively, the shaking/rocking could continue through- 15 out the collection provided that accuracy of the weight readings could be assured.

Typically blood bank standards require that blood collections must be completed in a set period of time (20 minutes maximum for current US regulations), smaller volumes of 20 collection can tolerate a slower flow rate. In some embodiments, the blood collection device measures the flow rate and compares it against a computed constant, equal to a minimum flow value for the set period of time described above. As a result, if the required volume is greater, the flow 25 rate must be greater to accomplish the fill in the set period of time (e.g., 20 minutes). If the required volume is less, the flow rate can be slower.

The blood collection device 106 can also include a barcode scanner 116 configured to read a barcode as an input 30 to the device. For example, donation ID's unique to individual donors can be scanned during the blood collection process to keep track of all collection events related to that unique donation ID. In one embodiment, the donation ID can be represented as a barcode 120 located on blood 35 donation bag 118.

The blood collection device 106 can be in communication with control system 108 during all steps of the blood collection process described above (e.g., calibration, blood collection, scrub and dry timing, and completion of the 40 blood draw). The blood collection device and control system can communicate via any technology known in the art, such as wirelessly through a WiFi or Bluetooth connection, or through a wired Ethernet connection. The control system can comprise a computer having all the necessary hardware 45 (e.g., CPU, memory, data storage, etc.) required to execute a data collection and management software.

Scrub Timer

In some embodiments, the blood collection device 106 can include a scrub timer 122. The scrub timer can be 50 configured to aid a phlebotomist in cleaning and preparing a needle entry site prior to blood collection. Some blood collection requirements or guidelines require that a needle entry site of the patient be scrubbed or cleaned for a certain period of time. For example, prepping for a blood collection 55 typically involves disinfecting the tissue around the needle entry site for at least 30 seconds with a 70% or higher alcohol swab, or alternatively, with an iodine solution. The tissue can then be dried before the blood collection process begins. If this disinfecting step is skipped, or if the phle- 60 botomist does not scrub the tissue entry site for the proper amount of time, the blood collected from that patient can be compromised.

Referring still to FIG. 1, a scrub timer 122 can be implemented in the blood collection device 106. The scrub 65 timer 122 can be a visual timer displayed on the GUI 110 (e.g., in the form of a countdown or other visual indicator),

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or alternatively can be an audible timer that is conveyed to the user or phlebotomist with spoken words, beeping, or other sounds. In some embodiments, the duration of the scrub timer can be pre-set by a user or the phlebotomist, depending on the desired scrub time. In other embodiments, the scrub timer can include both a first timer that tracks the scrubbing or disinfecting process, and second timer that tracks drying of the tissue around the needle entry site after the scrub, or a second scrub. The scrub timer 122 can optionally include a countdown timer before or after each of the first and second timers, to give a user or phlebotomist time to prepare for impending action. The scrub timer 122 can optionally include a manual and/or automated restart function, in which the scrub and/or dry timer is restarted in the blood collection device due to non-compliance. For example, a phlebotomist can manually restart the scrub and/or dry timer if the needle entry site was not prepared properly during the scrub time period, or alternatively, the blood collection device can automatically restart the scrub and/or dry timer if the blood collection process isn't started within a pre-determined period following completion of the scrub and/or dry timer.

FIG. 2 is a flowchart 200 describing the use of the scrub timer described above. All references to a blood collection device or scrub timer in this section can refer to blood collection device 106 and scrub timer 122 of FIG. 1. At step 202 of flowchart 200, a user of a blood collection device, such as phlebotomist, can initiate a blood collection process on the blood collection device. The user can, for example, turn on the blood collection device and push a button on the device to start the process.

Next, at step 204 of flowchart 200, the blood collection device can optionally start a "prepare to scrub" timer. This "prepare to scrub" timer can be displayed or audibly presented to the user to prepare them for the next step. For example, the "prepare to scrub" timer can be a short countdown, e.g., 5 seconds, to indicate to the user of the blood collection device that the scrub step is about to begin. In some embodiments, there is no "prepare to scrub" timer and the blood collection device goes directly from step 202 to step 206, below.

At step 206 of flowchart 200, the blood collection device can start the scrub timer. As described above, the duration of the scrub timer can be pre-set by the user, and can be a visual countdown or timer, or optionally can be audible words, beeps, or sounds. If the scrub timer is a visual countdown or running timer displayed on a GUI of the blood collection device, the user can look at the device to see how much time remains or has passed in the scrub. When the scrub timer begins in step 206, the user or phlebotomist can begin scrubbing the patient's skin surrounding the needle entry site, and can stop the scrubbing process when the scrub timer expires (or reaches the pre-configured scrub time). Scrubbing during the entire duration of the scrub timer ensures that proper scrub protocol has been followed by the phlebotomist.

In some scenarios, a phlebotomist may be required to perform a secondary scrub, or alternatively, may be required to dry the tissue around the needle entry site after the initial scrub. For example, some alcohol based scrubs require that the skin be dried before a needle is inserted into the patient. Alternatively, if an iodine solution is used for the initial scrub, some blood centers require a secondary scrub to further disinfect the patient. In either of these instances, steps 208 and 210 can be optionally implemented with a scrub timer feature of a blood collection device during a blood collection process.

At step **208** of flowchart **200**, the blood collection device can optionally start a "prepare to dry" timer. This "prepare to dry" timer can be displayed or audibly presented to the user to prepare them for the next step. For example, the "prepare to dry" timer can be a short countdown, e.g., 5 seconds, to indicate to the user of the blood collection device that the drying step is about to begin. In some embodiments, the "prepare to dry" timer can be replaced with a second "prepare to scrub" timer if a second scrub is required.

At step **210** of flowchart **200**, the blood collection device 10 can start the dry timer. As described above, the duration of the dry timer can be pre-set by the user, and can be a visual countdown or timer, or optionally can be audible words, beeps, or sounds. If the dry timer is a visual countdown or running timer displayed on a GUI of the blood collection 15 device, the user can look at the device to see how much time remains or has passed in the drying process. When the dry timer starts in step **210**, the user can begin the drying process, and can stop the drying process when the dry timer expires (or reaches the pre-configured dry time). As with 20 step **208**, the dry timer can be replaced with an optional second scrub timer if a second scrub is required.

At step **212** of flowchart **200**, the scrub and/or dry timer can manually or automatically be restarted. For example, if the phlebotomist fails to comply with the scrub and/or dry 25 timer and realizes the non-compliance, the phlebotomist can interface with the blood collection device to restart the scrub and/or dry timer (e.g., by pushing a button on the device). Alternatively, the blood collection device can automatically restart the scrub and/or dry timer if for example, the phle-30 botomy process does not begin within a predetermined time period following the completion of the scrub and/or dry time period.

Finally, at step **214** of flowchart **200**, the phlebotomy process can begin, and blood can be drawn from the patient. 35 Steps **202-212** above can be implemented in a scrub timer of the blood collection device to ensure that proper scrub protocol is followed, thereby decreasing the chances that the blood collected from the patient is rejected for failing to follow scrub protocol. 40

When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature 45 or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or 50 element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no intervening features or elements present. Although described or 55 shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or 60 underlie the adjacent feature.

Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include 65 the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms

"comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

Although the terms "first" and "second" may be used herein to describe various features/elements, these features/ elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/-0.1%of the stated value (or range of values), +/-1% of the stated value (or range of values), +/-2% of the stated value (or range of values), +/-5% of the stated value (or range of values), +/-10% of the stated value (or range of values), +/-10% of the stated value (or range of values), +/-10% of the stated value (or range of values), +/-10% of the stated value (or range of values), +/-10% of the stated value (or range of values), +/-10% of the stated value (or range of values), +/-10% of the stated value (or range of values), +/-10% of the stated value (or range of values), etc.

Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As 30

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mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively 5 by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement 10 calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described 15 herein, will be apparent to those of skill in the art upon reviewing the above description.

What is claimed is:

comprising:

- initiating, in a blood collection device, a scrub timer having a scrub time period;
- during the scrub time period, disinfecting skin tissue of the patient at a needle entry site with a disinfectant; and 25 after the scrub time period has elapsed, beginning a blood draw process with the blood collection device.

2. The method of claim 1, further comprising emitting one or more audible beeps from an audible output of the collection device during the scrub period.

3. The method of claim 1, further comprising emitting one or more audible beeps from an audible output of the collection device to indicate the start of the scrub period.

4. The method of claim 1, further comprising audibly counting down the scrub time period with an audible output 35 of the collection device.

5. The method of claim 1, further comprising visibly counting down the scrub time period with a graphical user interface of the collection device.

6. The method of claim 1, further comprising emitting a 40 series of audible beeps counting down the scrub period with an audible output of the collection device.

7. The method of claim 1, further comprising: initiating, in the blood collection device immediately after the scrub time period has elapsed, a prepare to dry timer having a 45 prepare to dry time period; and counting down the prepare to dry period.

8. The method of claim 7, further comprising emitting one or more audible beeps from an audible output of the collection device to indicate a start of the prepare to dry time 50 period.

9. The method of claim 7, further comprising audibly counting down the prepare to dry time period with an audible output of the collection device.

10. The method of claim 7, further comprising emitting 55 one or more audible beeps counting down the prepare to dry time period with an audible output of the collection device.

11. The method of claim 7, further comprising visibly counting down the prepare to dry time period with a graphical user interface of the collection device.

12. The method of claim 1, further comprising: initiating, in the blood collection device immediately after the scrub time period has elapsed, a prepare to dry timer having a prepare to dry time period; during the prepare to dry period, performing a secondary wash of the skin tissue of the patient 65 at the needle entry site; and counting down the prepare to dry period.

13. The method of claim 1, further comprising: after the disinfecting tissue step, automatically initiating in the blood collection device a dry timer having a dry time period; and drying skin tissue of the patient at the needle entry site during the dry time period.

14. The method of claim 1, further comprising emitting one or more audible beeps from an audible output of the collection device during the scrub period.

15. The method of claim 1, further comprising emitting one or more audible beeps from an audible output of the collection device to indicate a start of the scrub period.

16. The method of claim 1, further comprising audibly counting down the scrub time period with an audible output of the collection device.

17. The method of claim 1, further comprising visibly counting down the scrub time period with a graphical user interface of the collection device.

18. The method of claim 1, further comprising emitting a 1. A method of collecting blood from a patient, the method 20 series of audible beeps counting down the scrub period with an audible output of the collection device.

> 19. The method of claim 1, further comprising; before the scrub time period, initiating, in a blood collection device, a prepare to scrub timer having a prepare to scrub time period; and counting down the prepare to scrub time.

> 20. The method of claim 1, further comprising automatically restarting the scrub timer if the blood draw process does not begin within a pre-determined time period following the scrub time period.

> 21. A method of collecting blood from a patient, the method comprising:

- initiating, in a blood collection device, a scrub timer having a scrub time period;
- visibly and/or audibly counting down the scrub timer during the scrub time period with a graphical user interface and/or an audible output of the blood collection device;
- automatically initiating, in the blood collection device after the scrub time period has elapsed, a dry timer having a dry time period;
- visibly and/or audibly counting down the dry timer during the dry time period with the graphical user interface and/or the audible output of the blood collection device; and
- beginning a blood draw process with the blood collection device after the dry time period has elapsed.

22. The method of claim 21. further comprising initiating, in the blood collection device immediately before the scrub time period, a prepare to scrub period; and visibly or audibly counting down the prepare to scrub period with the graphical user interface or the audible output of the blood collection device.

23. The method of claim 21, further comprising emitting one or more audible beeps from an audible output of the blood collection device before initiating the dry time period.

24. The method of claim 21, further comprising emitting one or more audible beeps from an audible output of the blood collection device before initiating the scrub time period.

25. The method of claim 21, further comprising initiating, in the blood collection device immediately after the scrub time period has elapsed, a prepare to dry timer having a prepare to dry time period; and visibly or audibly counting down the prepare to dry period with the graphical user interface or the audible output of the blood collection device.

26. The method of claim 1 wherein the disinfectant comprises an alcohol solution.

US 11,4 11 27. The method of claim 1 wherein the disinfectant comprises an iodine solution.

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